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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,466	03/27/2001	Sean Lee	099866/9	1836

31013 7590 12/19/2006

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	09/818,466	LEE ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *171-200* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *171-200* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/3/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Non-Final Office Action, Applicant's Arguments/Remarks and the request for extension of time (3 months-granted), all filed 08/31/06 is acknowledged.

Claims 171-200 are pending in this action. New claims 171-200 have been added. Claims 135-170 have been cancelled. Claims 1-134 were previously cancelled. Claims 171-200 stand rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 171-200 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee *et al.* (WO 99/37287) in view of LaTorre *et al.* (U.S. Patent No. 6,517,863 B1) and further in view of Vatter *et al.* (U.S. Patent No. 6,224,888 B1).

The instant invention is drawn to a cosmetic composition comprising bioactive glass and a substantially anhydrous cosmetic formulation, wherein said bioactive glass comprises from about 30% to about 96% silicon dioxide (SiO_2), from about 4% to about 46% calcium oxide (CaO), from about 1% to about 15% phosphorus oxide (P_2O_5) and up to about 35% sodium oxide (Na_2O), all by weight of said bioactive glass, with the proviso that said bioactive glass does not comprise ions of silver, copper or zinc, wherein said bioactive glass comprises from about 0.05% to about 30% by weight of said cosmetic composition, wherein said cosmetic formulation is selected from the group consisting of lip products, face powder products, hair care products, deodorant products and soap products, and wherein said composition does not result in a significant skin sensitivity response when applied.

Lee *et al.* ('287) teach a bioactive glass composition and method for the treatment of inflammation in skin conditions comprising topical application of a particulate bioactive glass mixed with a topical medicinal carrier to the site of the skin disorder (see page 2, lines 10-13) and Abstract.

The particulate bioactive glass composition typically comprises SiO_2 (40-86%), CaO (10-46%), Na_2O (0-35%), P_2O_5 (2-15%), CaF2 (0-25%), B_2O_3 (0-10%), K_2O (0-8%), and MgO (0-5%) (pg. 3, lines 7-19); (Claim 1).

The preferred composition of the bioactive glass is SiO_2 (45%), CaO (24.5%), Na_2O (24.5%) and P_2O_5 (6%) (pg. 3, lines 20-26); (Claim 5).

These bioactive glass formulations read on the bioactive composition claimed herein, since they are comprised of the same components, used in similar amounts as claimed.

The bioactive glass and topical treatment can be combined in any pharmaceutically acceptable carrier to facilitate application to the skin (pg. 4, lines 22-23).

The blend of bioactive glass comprises about 20 to about 80% of bioactive glass (pg. 5, lines 13-15).

The preferred particle size range for the bioactive glass is small and not greater than 90 microns. Particle sizes less than 20 microns as well as less than 2 microns can also be used (pg. 4, lines 9-13).

Typical treatment comprises liberally applying a film of the bioactive glass containing composition to the inflamed area, optionally with gentle massage to work the composition into the skin (pg. 6, lines 1-6).

Since the bioactive glass compositions of Lee *et al.* are intended for topical application to the skin, the compositions would read on the skin and hair products claimed in independent claims 171 and 186.

Lee *et al.* do not teach how the bioactive glass is prepared, such as melt-derived or sol-gel derived.

LaTorre *et al.* ('863) teach compositions and methods for treating nails and adjacent tissues comprising particles of bioactive glass that have anti-microbial properties (see Abstract).

LaTorre *et al.* teach that the bioactive glass composition can be prepared in several ways to provide melt-derived glass, sol-gel derived glass, and sintered glass particles. The sintered particles may be in sol-gel derived, or pre-reacted melt-derived form. Molten glass can be fritted and milled to produce a small particulate material (col. 4, lines 33-45). Particulate non-interlinked bioactive glass is preferred; that is the glass is in the form of small, discrete particles (col. 4, lines 20-32). The bioactive glass can be in the form of a suspension, lotion, cream (water-in-oil emulsion), gel or extract (col. 4, lines 51-67).

According to LaTorre *et al.*, bioactive glasses are well known to those skilled in the art. The glass preferably includes between 40 and 86% by weight of silicon dioxide (SiO_2), between about 0 and 35% by weight of sodium oxide (Na_2O), between about 4 and 46% by weight calcium oxide (CaO), and between about 1 and 15% by weight phosphorous oxide (P_2O_5) (col. 3, line 50 – col. 4, line 10).

LaTorre *et al.* disclose that the bioactive glass compositions can include additional components, such as antibiotics, antivirals, antifungals, biotin, collagen, amino acids, proteins, vitamins, penetration enhancers, permeation/binding agents, dyes, fragrances and other cosmetically useful additives (col. 2, lines 62-66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the melt-derived or sol-gel derived bioactive glass of LaTorre *et al.* within the bioactive glass compositions of Lee *et al.* One of ordinary skill in the art would be motivated to do so because LaTorre *et al.* teach bioactive glass compositions that can be prepared in several suitable ways to provide melt-derived glass, sol-gel derived glass, and sintered glass particles that are effective for the formation of small, discrete, non-interlinked

particles. The expected result would be an enhanced, particulate bioactive glass composition having effective antimicrobial properties.

The teachings of Lee *et al.* are delineated above. Lee *et al.* do not teach additives, such as jojoba oil, glycerin, parabens and pigments.

Vatter *et al.* ('888) teach cosmetic compositions comprising various additives, such as oils, waxes, pigments, preservatives, colorants, fragrances and the like. Suitable oils include *jojoba oil, mineral oil, castor oil, etc.* (see reference column 6, lines 19-35). Waxes include *carnauba, candelilla, ozokerite, microcrystalline waxes and mixtures thereof* (col. 8, lines 31-44). *Pigments, dyes and talc* are disclosed at column 10, line 64-col. 11, line 49. Vitamins taught include *Vitamin A and E* (col. 12, lines 20-29). *Glycerine* is disclosed at column 5, lines 8-13. Parabens, such as *methyl paraben and propyl paraben* are disclosed in various examples, particularly Example 14. Vatter *et al.* teach that the cosmetic compositions can be, for instance, in the form of foundations, eye shadows, blushers, lipstick, lipcare products, mascara, solutions, powders and the like (col. 2, lines 16-21); (col. 12, lines 2-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the various additives of Vatter *et al.* within the bioactive glass composition of Lee *et al.* because Vatter *et al.* expressly teach cosmetic compositions comprising routinely utilized additives (*i.e.*, oils, waxes, pigments, vitamins, preservatives for skin/hair/nails) and teach that such additives are suitable and beneficial for use in personal care

compositions (*i.e.*, skin). The expected result would be an effective cosmetic composition having added benefits for use in personal care applications.

Thus given the teachings of the cited art of record discussed above, the instant invention, when taken as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Pat. No. 4,814,165 Berg *et al.* 03/1989

Response to Arguments

Applicant's arguments filed 08/31/06 have been fully considered and were found to be partially persuasive.

- **35 U.S.C. §103(a) Rejection over LaTorre et al. (USPN 6,517,863) and Vatter et al. (USPN 6,224,888):**

Applicant argued, "LaTorre is directed to (1) nails, a hard surface which is not like skin or hair; (2) describes a formulation that does not need to be gentle to the skin since it is applied to nails rather than skin or hair; (3) describes a formulation that should be applied immediately and therefore cannot provide long-lasting antimicrobial effects for the cosmetic composition itself both prior to and after application and (4) describes a topical formulation that requires

sufficient water to be effective and thus is not substantially anhydrous. The '888 patent fails to cure the deficiencies of the '863 patent."

Applicant's arguments have been fully considered and were found partially persuasive. The LaTorre et al. reference has now been used as a secondary reference, rather than a primary reference, to show that it is known in the art to formulate melt-derived or sol-gel derived bioactive glass formulations. The primary reference, Lee et al. ('287) meets the requirements of the instant independent claims. The Lee et al. reference teaches bioactive glass compositions comprising SiO_2, CaO, Na_2O and P_2O_5 in similar or overlapping amounts as that claimed by Applicant (see for instance, pg. 3, lines 20-26); (Claim 5). The compositions of Lee et al. are intended for topical application upon the skin. The prior art teaches incorporation of the same components, for use in the same field of endeavor to treat similar problems as that desired by Applicant. It is also noted that the LaTorre et al. ('863) patent also recognizes and teaches bioactive glass compositions comprising SiO_2, CaO, Na_2O and P_2O_5 in similar amounts as instantly claimed, albeit bioactive glass composition for use in nail applications (see '863, col. 3, line 60 – col. 4, line 19). Applicant has not demonstrated any unexpected or superior results through the claimed combination of components since the prior art clearly teaches bioactive glass compositions comprised of the same elements and prepared by similar methods.

Burden is upon Applicant to establish that the prior art bioactive glass compositions would not provide for beneficial or effective results.

The instant invention remains unpatentable based on the explicit teachings of the prior art identified above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

December 02, 2006

HUMERA N SHEIKH
PRIMARY EXAMINER
TC-1600

hns